IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS INC.,	:	
Plaintiff,	:	
	:	
v.	:	**Civil Action No. 2:14-cv-02094-**
	:	**ES-MAH**
CELGENE CORPORATION,	:	
Defendant.	:	
	:	
	:	

PLAINTIFF MYLAN PHARMACEUTICALS INC.'S BRIEF IN OPPOSITION TO DEFENDANT CELGENE CORPORATION'S MOTION TO CERTIFY ORDER DENYING MOTION TO DISMISS FOR INTERLOCUTORY APPEAL

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INTRODUCTION

The Third Circuit and the Supreme Court have held that "economic realities rather than a formalistic approach must govern review of antitrust activity," and that the courts must attend to facts rather than "formalistic distinctions" in examining conduct under Section 2 of the Sherman Act. *See United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005) (quoting *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 466-67 (1992)). Yet Celgene advocates the "formalistic approach" of dismissing any refusal to deal claim that does not include an allegation of a prior course of dealing regardless of factual and economic context. In particular, Celgene calls for the courts to turn a blind eye to the distinctive circumstances of pharmaceutical products subject to REMS restrictions, where a branded company can prevent a prospective generic competitor from even filing an ANDA by blocking access to the samples necessary to perform the tests needed to gain regulatory approval for an AB-rated generic product. Consistent with the views of the FTC and every other court to address the exact issue before the Court, this Court properly rejected Celgene's argument.

Celgene's motion to certify that order for interlocutory appeal under 28 U.S.C. § 1292(b) fails to show any ground for granting such extraordinary relief without allowing the development of an evidentiary record concerning the "economic realities" of the case that would inform the legal analysis. Certification

would not advance the resolution of the case, moreover, because Celgene's proposed question is not dispositive here, where additional conduct beyond a pure unilateral refusal to deal is present, and where Mylan has alternative liability theories (such as denial of access to an essential facility) that Celgene's proposed appeal would not resolve. Rather, Celgene's proposed appeal would only serve to further its goal of delaying generic entry by delaying resolution of Mylan's claims. Celgene's motion should, accordingly, be denied.

ARGUMENT

"Congress intended that section 1292(b) should be sparingly applied." *Milbert v. Bison Labs., Inc.*, 260 F.2d 431, 433 (3d Cir. 1958). The party seeking an interlocutory appeal under this provision must show that the order appealed from "(1) involves a 'controlling question of law,' (2) offers 'substantial ground for difference of opinion' as to its correctness, and (3) if appealed immediately, 'materially advance[s] the ultimate termination of the litigation.'" *In re Blood Reagents Antitrust Litig.*, 756 F. Supp. 2d 637, 643 (E.D. Pa. 2010) (citation omitted); *Behrend v. Comcast Corp.*, Civil Action Nos. 03-6604, 07-218, & 07-219, 2007 U.S. Dist. LEXIS 67271, at *2-*3 (E.D. Pa. Sept. 11, 2007).

"The decision whether or not to grant certification is entirely within the district court's discretion, and even if all three criteria under Section 1292(b) are

met, the district court may still deny certification." *Avaya Inc. v. Telecom Labs, Inc.*, Civil Action No. 06-2490, 2012 U.S. Dist. LEXIS 59100, at *11 (D.N.J. Apr. 26, 2012) (internal marks and citations omitted). Courts ordinarily reject requests to certify or maintain interlocutory appeals at the motion to dismiss stage. *See In re Blood Reagents*, 756 F. Supp. 2d at 644 ("As a general rule, appellate courts do not grant interlocutory appeals from a motion to dismiss because it encourages 'piecemeal litigation.'") (citation omitted).

These principles all support denying Celgene's motion for interlocutory review. The Court's motion to dismiss order does not present a "controlling question of law" because the legal analysis of this case is inexorably bound up with the facts, the question Celgene proposes is not presented here, and the essential facilities doctrine provides an alternative legal theory to sustain Mylan's monopolization claims. The Court's reasoning likewise does not present substantial grounds for difference of opinion because it represents a straightforward application of controlling precedent, as shown by the fact that all three courts addressing the issue presented here have sustained the claims on a motion to dismiss. And an interlocutory appeal on one theory of liability would present significant risks of piecemeal litigation, meaning efficiency considerations

likewise favor adhering to the final judgment rule in this case. Celgene's motion should therefore be denied.

I. FORMULATION OF THE PROPER LEGAL RULE FOR REMS ABUSE CASES REQUIRES A FULLER FACTUAL RECORD

"[E]ven a legal question should be denied interlocutory appeal if resolution of the question requires a heavily fact-based analysis." *In re Vitamin C Antitrust Litig.*, No. 06-MD-1738, 2012 U.S. Dist. LEXIS 16475, at *8 (E.D.N.Y. Feb. 8, 2012) (internal marks and citation omitted). "[W]hat the framers of § 1292(b) had in mind is more of an abstract legal issue or what might be called one of 'pure' law, matters the court of appeals 'can decide quickly and cleanly without having to study the record.'" *McFarlin v. Conseco Servs., LLC*, 381 F.3d 1251, 1258 (11th Cir. 2004) (quoting *Ahrenholz v. Bd. of Trustees of the Univ. of Ill.*, 219 F.3d 674, 677 (7th Cir. 2000)).

Celgene repeatedly claims that the case presents a pure question of law. *See* D.E. No. 58-1 at 1, 4-5, & 9. That is incorrect. As *Dentsply* and other decisions note, antitrust cases under the rule of reason, like this case, are by definition fact-intensive and attuned to the specifics of the industry and conduct at issue. *See Dentsply*, 399 F.3d at 189. *Accord L.A. Mem'l Coliseum Comm'n v. NFL*, 726 F.2d 1381, 1391 (9th Cir. 1984) ("Rule of reason analysis calls for a thorough investigation of the industry at issue and a balancing of the arrangement's positive

and negative effects on competition.") (internal marks and citations omitted). The determination of any rule of decision for this case, let alone for all future cases, necessarily demands a full factual record to understand the consequences of any rule for refusal to deal claims where the refusal functionally prevents any AB-rated generic entry. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 283 (3d Cir. 2012) ("Antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue.") (internal marks and citation omitted), *cert. denied*, 133 S. Ct. 2025 (2013). *See generally United States v. Microsoft Corp.*, 253 F.3d 34, 58-59 (D.C. Cir. 2001) (*en banc*) (describing proper analysis of monopolization claims).

In particular, the case hinges on the same factual issue Judge Hillman noted in *Actelion* and this Court cited in its opinion on Celgene's motion to dismiss: whether Mylan "can prove that [Celgene is] motivated not so much by safety concerns but instead motivated by the desire to use the REMS or REMS equivalent, to use exclusive distribution agreements and to use a[n] otherwise legitimate refusal to deal together to maintain and extend a monopoly[.]" *See Actelion Pharm. Ltd. v. Apotex, Inc.*, No. 12-5743, D.E. No. 93 at 117:1-6 (D.N.J. Oct. 23, 2013)); D.E. No. 56 at 14:2-15:8. It is thus impossible for a final rule to be announced in the absence of an evidentiary record concerning the purpose and effect of

Celgene's conduct, which can only be adduced through discovery, as both this Court and the *Actelion* court noted. *See id*. *See also Actelion*, D.E. No. 93 at 115:14-19 ("When I read Trinko and Aspen Highlands, I look at those cases through the lens of – the case now almost a hundred years old, Colgate and Otter Tail, it suggests to me that the proper application of the antitrust laws is almost always a fact-specific one and, indeed, an industry-specific one.").

The Court (and the Third Circuit) needs a full record on the competitive realities of the pharmaceutical industry generally and on the products and conduct at issue here in particular to come to a final conclusion, so the question is not a pure question of law and there is a real risk that an insufficient record would prevent the Third Circuit from being able to give appropriate review to the legal questions in their proper factual context. That consideration counsels strongly against certification, even if the question proposed is a question of law. *See LePage's Inc. v. 3M*, Civil Action No. No. 97-3983, 1998 U.S. Dist. LEXIS 343, at *7 (E.D. Pa. Jan. 9, 1998) ("[I]f the Third Circuit should wish to reconsider its position in *SmithKline*, it would be better able to do so on the basis of a completed record.").

The *Wyndham* case Celgene relies on presents a perfect foil to this one: that case involved a pure question of whether a statute did or did not authorize the FTC

to police a category of conduct. *See FTC v. Wyndham Worldwide Corp.*, 10 F. Supp. 3d 602, 634 (D.N.J. 2014); *cf.* D.E. No. 58-1 at 3 & 8. Unlike that administrative law question, this case requires application of what is essentially a body of common law based on rigorous economic and factual analysis. *See Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 899 (2007) ("From the beginning the Court has treated the Sherman Act as a common-law statute."). Since there is no developed evidentiary record or economic testimony to aid the courts in formulating an appropriate rule for when a duty to deal exists in cases where REMS programs practically bar all means of generic entry other than obtaining samples from the brand company, the record is not sufficiently developed to certify an interlocutory appeal.

II. CELGENE'S PROPOSED QUESTION IS NOT PRESENTED IN THIS CASE

Celgene's proposed question is "[w]hether a prior, voluntary course of dealing is required to allege an actionable refusal to deal under Section Two of the Sherman Act, 15 U.S.C. § 2." D.E. No. 58-1 at 9. The question as framed shows that an interlocutory appeal is inappropriate here, for the answer to that question would neither dispose of nor even narrow this case.

First, contrary to Celgene's assertion, Mylan does allege that Celgene engaged in voluntary dealings with others, so there was voluntary dealing, albeit

not with Mylan, as the Court notes. *See* D.E. No. 56 at 17:24-18:2. Specifically, Mylan alleges that Celgene provided samples of Thalomid and Revlimid to research organizations, meaning it has voluntarily made samples available to other non-customer entities outside of its REMS program. *See* Compl. ¶¶ 65, 71, & 160-63. This is identical to the allegations in *Actelion* that Judge Hillman allowed to go forward. *See Actelion*, D.E. No. 93 at 49:21-50:5 (noting allegations of sales to research organizations). Because Mylan has alleged a prior course of dealing, Celgene's proposed question is not relevant to deciding this case.

Second, the cases Celgene cites (D.E. No. 58-1 at 1 n.1) are purely unilateral refusal to deal cases; here, as the Court noted, there is the added element of Celgene's restrictions on downstream distributors, which makes this more analogous to a concerted refusal to deal case. *See* D.E. No. 56 at 14:12-24 & 33:4-12. The precedent Celgene relies on is thus inapposite. *See W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 103 (3d Cir. 2010) (noting more rigorous scrutiny for conduct involving multiple actors).

Third, Celgene claims that Mylan has essentially admitted that its claims would not survive in the Second or Eleventh Circuit (or circuits with similar precedent). *See* D.E. No. 58-1 at 1 & 4-6. This is incorrect. Mylan's suit is consistent with all applicable precedents, and the cases Celgene cites simply did

not address the circumstances presented here where a refusal to deal functionally bars generic entry from occurring at all. For example, as this Court noted in its opinion, the Second Circuit's *Elevator* decision "focus[ed] . . . on the willingness to forsake short-term profits for an anticompetitive end" and "does not address whether other factors could also indicate such a willingness." *See* D.E. No. 56 at 16:5-19 (discussing *In re Elevator Antitrust Litig.*, 502 F.3d 47 (2d Cir. 2007)).

Even the Second Circuit's *Adderall* case, the sole case concerning pharmaceuticals, simply dealt with failure to perform a supply agreement in a context where the performance that occurred actually permitted some new entry, not conduct that would prevent the generic companies from bringing AB-rated products to market altogether. *See In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 135 (2d Cir. 2014) (noting actual entry and sales below retail price to competitors). Indeed, two of the cases dealt with the exact fact-pattern presented in *Trinko*: antitrust claims in circumstances where the Telecommunications Act provided a means of access. *See Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 672-73 (D.C. Cir. 2005); *Covad Commc'ns Co. v. BellSouth Corp.*, 374 F.3d 1044, 1049-50 (11th Cir. 2004). The context here is so different – as noted by Judge Hillman in *Actelion* – that the cases Celgene cites cannot fairly be read to apply to

REMS abuse issues like those raised here. *See Actelion*, D.E. No. 93 at 115:22-23 ("The FDA is not the FCC. It's a different environment.").[1]

Celgene is thus incorrect that Mylan's claims would not survive under the out-of-circuit case law it cites. Because Mylan states a claim under any standard the Third Circuit may plausibly adopt, and Celgene's proposed appellate question does not dispose of Mylan's claims, Celgene has failed to meet its burden of identifying a controlling question of law, let alone one whose resolution would advance the disposition of this case.

[1] Several of the cases Celgene cites also do not establish the legal rules it claims. Most importantly, in the D.C. Circuit's *Covad* case, the court expressly distinguished a refusal to cooperate claim (which required a prior course of dealing) from a claim based on refusal by the defendant to provide a commercial service at market price; the court held that claim survived even though a refusal to cooperate claim could not. *See* 398 F.3d at 675-76. Here, Mylan seeks to purchase samples at market price, not to require ongoing cooperation, so its claim is analogous to the *Covad* claim that survived. Celgene also cites the *Novell* case, but the passage cited is dicta because there was a prior course of dealing between Microsoft and Novell, and in any event Microsoft's alleged refusal only resulted in a nine-month delay in Novell's entry, not complete exclusion. *See Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1068-69 & 1076 (10th Cir. 2013). The *LiveUniverse* case is non-precedential, and the passage is also dictum because the claim would have been dismissed regardless of the prior course of dealing issue. *See LiveUniverse, Inc. v. MySpace, Inc.*, 304 Fed. Appx. 554, 555 & 557 (9th Cir. 2008). The underlying Ninth Circuit case law in fact treats prior course of dealing as just one factor in the analysis, and was also developed in the telecommunications context where the regulatory scheme provided access. *See MetroNet Servs. Corp. v. Qwest Corp.*, 383 F.3d 1124, 1130-34 (9th Cir. 2004).

III. CELGENE'S PROPOSED QUESTION WOULD NOT DISPOSE OF THIS CASE BECAUSE IT WOULD NOT RESOLVE THE ESSENTIAL FACILITIES ISSUE

Certification is also inappropriate in this case because an alternative legal theory is available to sustain the monopolization claims here. *See Piazza v. MLB*, 836 F. Supp. 269, 270-71 (E.D. Pa. 1993) (certification denied in light of alternative legal theory for sustaining antitrust claim). Mylan alleged denial of access to an essential facility in its Complaint and defended it as a theory of Section 2 liability in its briefing on Celgene's motion to dismiss. *See* Compl. ¶¶ 224-57; D.E. No. 24 at 23-27. The Court allowed Mylan's essential facility counts to go forward, and it cited case law recognizing that the doctrine provides a basis for a refusal to deal claim that does not depend on any prior course of dealing. *See* D.E. No. 56 at 33:8-9; *Only v. Ascent Media Grp., LLC*, No. 06-2123, 2006 WL 2865492, at *4 n.7 (D.N.J. Oct. 5, 2006) (noting essential facilities as a separate theory from termination of a prior course of dealing). Mylan would thus still have federal and state antitrust claims and state business tort claims that would require identical discovery and would proceed similarly at trial. So even if the Third Circuit agreed with Celgene on general refusal to deal claims, that would not end the case, or even the monopolization claims, since Celgene's has not proposed any appellate question that addresses the essential facilities doctrine.

Celgene does not and cannot argue that there is any ambiguity regarding the essential facilities doctrine in this Circuit. The Third Circuit has recognized the theory and definitively announced the necessary elements, none of which requires a prior course of dealing. *See Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 748 (3d Cir. 1996) (quoting *Del. Health Care, Inc. v. MCD Holding Co.*, 893 F. Supp. 1279, 1287 (D. Del. 1995)). Whatever criticism the doctrine may have generated from commentators, the *Trinko* Court expressly stated that it was not addressing the doctrine, so *Ideal Dairy* and *Delaware Health Care* remain good law. *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004) ("[W]e find no need either to recognize [the essential facilities doctrine] or to repudiate it here."). *Accord Nobody in Particular Presents, Inc. v. Clear Channel Commc'ns, Inc.*, 311 F. Supp. 2d 1048, 1109-14 (D. Colo. 2004) (allowing essential facilities claim post-*Trinko*).

The essential facilities doctrine thus provides an independent basis for Mylan's monopolization claims. Since Mylan states a monopolization claim under controlling law regardless of whether the Third Circuit agrees with Celgene's proposed rule for unilateral refusal to deal cases not involving essential facilities, Celgene's proposed interlocutory appeal would not limit discovery, streamline trial, or otherwise simplify the case. *Cf.* D.E. No. 58-1 at 7-9. The fact that Mylan has

an additional theory of Section 2 liability based on settled Third Circuit law further rebuts any claim that the case hinges on a controlling question of law or that an interlocutory appeal would significantly advance the resolution of the litigation.[2]

IV. CELGENE DOES NOT IDENTIFY ANY LEGAL AMBIGUITY JUSTIFYING AN INTERLOCUTORY APPEAL

As the FTC's amicus demonstrates (D.E. No. 26-3 at 9-15), there is insufficient ground for difference of opinion in how to apply controlling precedent to this case. "The allegations in this case fit within the Supreme Court's existing refusal to deal precedent in *Otter Tail* and *Aspen Skiing*, as clarified in *Trinko*." *Id.* at 9. The out-of-circuit cases Celgene cites do not deal with the issue of complete obstruction of generic entry. By contrast, every case considering conduct that prevents effective filing of an ANDA or otherwise precludes AB-rated generic entry has found a claim was stated, including the *Lannett* and *Actelion* cases on REMS abuse as well as the *TriCor*, *Suboxone*, and *Doryx* decisions on use of

[2] In addition to the essential facilities doctrine, Mylan's state law claims would not necessarily be determined by any rule concerning unilateral refusal to deal under the Sherman Act. And should Celgene be permitted to appeal the Court's order, Mylan would seek revival of its Section 1 claims. Both sets of claims would require the parties to engage in virtually identical discovery, pre-trial, and trial proceedings. Thus, no efficiencies would be gained by an interlocutory appeal because Mylan would still have multiple claims beyond those Celgene proposes to have the Third Circuit review.

strategic product modifications to prevent generic entry and the myriad decisions on improper Orange Book listings, sham litigation, and other patent abuses. *See Actelion*, D.E. Nos. 90 & 93; *Lannett Co. v. Celgene Corp.*, No. 08-3920, D.E. No. 42 (E.D. Pa. Mar. 30, 2011).[3]

Significantly, *Broadcom* and *Otter Tail* clearly allowed claims where there was no prior course of dealing with the specific plaintiffs. The voluntary offer made in *Broadcom* was not to the plaintiff directly, so Celgene's claimed distinction fails. *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 304-05 & 316 (3d Cir. 2007). The prior dealing in Broadcom is not materially different from Celgene's prior provision of samples to research organizations or commercial sales to wholesalers, so even adopting Celgene's construction of *Broadcom* would not result in a different outcome as Celgene has engaged in prior dealings with others, and only refuses profitable market-price sales to Mylan in order to prevent competition. And Celgene continues to misstate *Otter Tail*, where the utility never dealt with the municipalities as competitors; it dealt with the residents as utility

[3] *Accord, e.g.*, *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) (*TriCor*); *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, Civ. No. 12-3824, 2013 U.S. Dist. LEXIS 152467 (E.D. Pa. June 11, 2013) (*Doryx*); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2014 WL 6792663 (E.D. Pa. Dec. 3, 2014); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340 (D.N.J. 2009).

customers. *See Otter Tail Power Co. v. United States*, 410 U.S. 366, 371 & 377-78 (1973). Once again, there was no course of dealing with the competitor-plaintiff.

Further, the significance of the termination of the "presumably profitable" prior course of dealing in *Aspen Skiing* itself was that it demonstrated that Ski Co.'s conduct made no economic sense absent the exclusion of competition. *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 608 (1985). *Accord Trinko*, 540 U.S. at 409. The same is true here; Celgene's refusal to allow Mylan to pay full price (while providing indemnification and safety assurances through its FDA-approved protocols) makes no economic sense absent its exclusionary impact. It is thus clear under controlling precedent that there can be a refusal to deal claim in these circumstances even absent a prior course of dealing between Celgene and Mylan. As the Court observed succinctly, "it appears that the *Trinko* Court considered these facts not for their independent significance, but rather for what they *suggest*: A willingness to engage in irrational, anticompetitive conduct." D.E. No. 56 at 12:14-17.[4]

[4] Celgene tries to use the *Suboxone* decision to claim that there is a division of authority within this Circuit. D.E. No. 58-1 at 6-7. But *Suboxone* only treated the absence of a prior course of dealing as one factor, and did so in a context where it was undisputed that generics were capable of entry with AB-rated products (and in fact had entered) despite the refusal to deal. 2014 WL 6792663, at *15. It expressly distinguished the circumstances where refusal to sell samples combined

There is thus sufficient guidance from controlling precedent to obviate any broader benefit in terms of development of the law from an immediate appeal here, contrary to Celgene's argument. *Cf*. D.E. No. 58-1 at 2 & 6-7. The fact that controlling precedent clearly supports allowing Mylan's claims to go forward thus provides a further basis to deny Celgene's request for an interlocutory appeal.

CONCLUSION

Because none of the prerequisites for certifying an interlocutory appeal are satisfied here, Celgene's Motion to Certify Order Denying Motion to Dismiss for Interlocutory Appeal should be denied.

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with distribution restrictions downstream would completely bar AB-rated generic entry. *Id*. at *16. Celgene's reliance on *Suboxone* shows that it cannot identify a meaningful division in authority within this Circuit.

Dated: January 20, 2015

Respectfully submitted,

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